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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,316	04/02/2004	Xingbai He	TTC-005XX	1106
207 7590 12/17/2007 WEINGARTEN, SCHURGIN, GAGNEBIN & LEOVICI LLP TEN POST OFFICE SQUARE BOSTON, MA 02109			EXAMINER CWERN, JONATHAN	
			ART UNIT 3737	PAPER NUMBER
			MAIL DATE 12/17/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/817,316	Applicant(s) HE ET AL.	
	Examiner Jonathan G. Cwern	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 19-27 and 35-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 28-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/11/07, 9/20/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Invention I in the reply filed on 11/30/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 19-27 and 35-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/30/07.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: In figure 1A, reference numeral 11 is missing. In figure 1B, reference numerals 14 and 16 are missing. If present, the reference numerals are not clear enough to read.. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If

the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: reference numeral 46 in Figure 1C; reference numeral 462 in Figure 3; and reference numeral 700 in Figure 4. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: on page 12, lines 9-10, the term "display controller 44" appears to be incorrectly labeled. In Figure 1c, the display controller is labeled as reference numeral 42.

In addition, the status of cited patent applications should be updated, for example on pages 9 and 11.

Appropriate correction is required.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claims 7-8, 13-14, 16, and 28-34 are objected to because of the following informalities: In claim 5, on the last line, the word "movement" should be inserted after "tissue". In claim 7, the phrase "the first region" and the phrase "the second region" lack antecedent basis. In claim 8, the word "border" is misspelled. In claim 13, the word "further" is misspelled. In claim 14, line 3, the word "heart" is misspelled. In addition, on line 4, "a heart" should be changed to "the heart" in view of line 3. In claim 18, the phrase "the echocardiography imaging operations" lacks antecedent basis. In claim 28, line 8, the word "data" is misspelled. In claim 29, lines 1-2, "the step of performing a Doppler imaging process" lacks antecedent basis. In claim 30, the word "data" is misspelled. In claim 32, "the gates" lacks antecedent basis. Claim 33 currently depends on claim 18, not claim 28. If this is correct, "a heart" should be changed to "the heart". In claim 34, the word "performing" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is unclear as to whether the B-mode image is provided by the "Doppler" imaging system and if so why is it labeled as a "Doppler" imaging system. There is no connection provided between the steps- for example- the claim fails to set forth that the gate is formed using the reference image; the claim fails to set forth what is used to form the Doppler data; and the claim fails to set forth that the displacement data is determined from the Doppler data. In addition, the preamble of claim 1 is directed to measuring tissue movement which is not consistent with the limitation in the claims of determining displacement of the tissue.

Claim 4 is incomplete in that the claim fails to initially set forth a step of measuring the data to be displayed. As a suggestion, perhaps claims 3 and 4 could be combined.

The term "gold standard image set" in claim 18 is a relative term which renders the claim indefinite. The term "gold standard image set" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In addition, it is unclear as to applicant's intent for the claim. Even with a

further definition for "gold standard image set", the language of the claim is still confusing and unclear.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12, 14-18, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mo et al. (US 6450959) in view of Criton et al. (US 5800356).

Mo et al. show methods and apparatus for simultaneous B-mode and multi-gate spectral Doppler imaging by an ultrasound scanner system (column 2, lines 50-55). Two or more independent Doppler beams are generated by the transmitter array to sample different vessel locations, each beam being multi-gated (column 4, lines 60-65).

Figure 7 shows the two spectral lines in the same image frame. The spectral data is superimposed onto the B-image (tissue Doppler image, column 4, lines 45-55). Also, an ECG signal can be used as a trigger signal (column 5, lines 25-26). Mo et al. also mention that this device would be useful for monitoring flow profile changes in conjunction with vessel wall movements over the cardiac cycle (column 1, lines 58-63). Regarding claim 18, it is well known and expedient to use standard operating guidelines to perform echocardiography imaging operations. However, Mo does not go into specific details of tissue motion.

Criton et al. disclose an ultrasonic diagnostic imaging system with Doppler assisted tracking of tissue motion. Criton et al. teach identifying the borders of the heart wall (column 1, lines 55-65); using automatic border detection (column 3, lines 5-20); measuring and displaying the displacement of the walls (column 6, line 64-column 7, line 15); obtaining and displaying velocity data (column 6, lines 5-15); identifying and displaying the direction of motion (column 6, lines 5-15); obtaining information over a time interval (column 3, lines 25-27); proving apical images with at least two chambers (Figure 2), and short axis view of the heart (Figure 10).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used B-mode imaging and Doppler information to identify motion of the heart. Mo et al. briefly mention that their invention can be used to study vessel wall movements over the cardiac cycle (column 1, lines 58-63), but do not go into the specific details of calculating the tissue motion. Criton et al. provide a system and method to calculate and display tissue motion of the heart, and describe calculating and

displaying the tissue motion in detail. One of ordinary skill in the art could have used the system of Mo et al. to calculate tissue motion of the heart taught by Criton et al.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mo et al. (US 6450959) in view of Criton et al. (US 5800356) as applied to claim 1 above, and further in view of Heimdal et al. (US 7022078).

Heimdal et al. disclose a method and apparatus for spectral strain rate visualization. Heimdal et al. teach the use of a diagnostic ultrasound system to generate and display strain rate spectrums corresponding to the deformation of tissue (abstract).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have determined the strain rate of the tissue. Knowledge of the strain rate of the tissue motion of the heart provides additional information to the physician to properly diagnose heart malfunctions in the patient.

Claims 28-32, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mo et al. (US 6450959) in view of Criton et al. (US 5800356) and further in view of Dala-Krishna et al. (US 7211045).

Mo et al. show methods and apparatus for simultaneous B-mode and multi-gate spectral Doppler imaging by an ultrasound scanner system (column 2, lines 50-55). Two or more independent Doppler beams are generated by the transmitter array to sample different vessel locations, each beam being multi-gated (column 4, lines 60-65).

Figure 7 shows the two spectral lines in the same image frame. The spectral data is superimposed onto the B-image (tissue Doppler image, column 4, lines 45-55). Also, an ECG signal can be used as a trigger signal (column 5, lines 25-26). Mo et al. also mention that this device would be useful for monitoring flow profile changes in conjunction with vessel wall movements over the cardiac cycle (column 1, lines 58-63). However, Mo does not go into specific details of tissue motion.

Criton et al. disclose an ultrasonic diagnostic imaging system with Doppler assisted tracking of tissue motion. Criton et al. teach identifying the borders of the heart wall (column 1, lines 55-65); using automatic border detection (column 3, lines 5-20); measuring and displaying the displacement of the walls (column 6, line 64-column 7, line 15); obtaining and displaying velocity data (column 6, lines 5-15); identifying and displaying the direction of motion (column 6, lines 5-15); obtaining information over a time interval (column 3, lines 25-27); proving apical images with at least two chambers (Figure 2), and short axis view of the heart (Figure 10).

Dala-Krishna et al. disclose a method and system for estimating the volume of blood ejected from the left ventricle of the heart for the placement of permanent pacemaker electrodes. Dala-Krishna et al. teach that imaging wall motion will allow the pacemaker electrodes to be easily implanted into the heart (column 4, lines 15-22).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used B-mode imaging and Doppler information to identify motion of the heart. Mo et al. briefly mention that their invention can be used to study vessel wall movements over the cardiac cycle (column 1, lines 58-63), but do not go into

the specific details of calculating the tissue motion. Criton et al. provide a system and method to calculate and display tissue motion of the heart, and describe calculating and displaying the tissue motion in detail. One of ordinary skill in the art could have used the system of Mo et al. to calculate tissue motion of the heart taught by Criton et al.

It would have been obvious to one of ordinary skill in the art to have used the tissue motion information of the heart obtained by the combined device of Mo et al. and Criton et al. to aid in implanting a pacemaker. The use of wall motion information is highly desirable during the implantation procedure (Dala-Krishna, column 2, lines 60-67).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is 571-270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC

/Ruth S. Smith/
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Primary Examiner
Art Unit 3737